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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

JOHN HERZFELD, an individual,

Plaintiff,

vs.

TEVA PHARMACEUTICALS USA, INC. OMNIBUS WELFARE PLAN; QUANTUM HEALTH, INC. WHICH WILL DO BUSINESS IN CALIFORNIA AS COORDINATED HEALTHCARE; MERITAIN HEALTH, INC; MCMC, LLC; and AETNA LIFE INSURANCE CO.

Defendants.

CASE NO.: 2:18-CV-9784

COMPLAINT FOR:
(1) TO RECOVER BENEFITS DUE UNDER ERISA, ENFORCE AND/OR CLARIFY RIGHTS UNDER ERISA, AND ENFORCE THE TERMS OF ERISA, 29 U.S.C. § 1132(a);
(2) VIOLATION OF ERISA § 404; AND
(3) VIOLATION OF ERISA § 503

I. JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, 1332 and 1337, and ERISA § 502(e)(1), 29 U.S.C. § 1132(e)(1), as a result of the denial of benefits that Plaintiff John Herzfeld is entitled to under an ERISA-governed welfare benefit plan and breaches of fiduciary duties by each of the Defendants.

2. Venue is proper in this District pursuant to ERISA § 502(e)(2), 29

U.S.C. § 1132(e)(2), because the breaches occurred and caused consequences in this Judicial District. Plaintiff is a dependent of Jeffrey Herzfeld who, at all times relevant, was employed by Teva Pharmaceuticals USA, Inc., the sponsor of the Plan, in this Judicial District; Plaintiff received the denial of benefits at issue from the Plan in this District; Defendants regularly conduct business in this District and the events giving rise to this case took place in this judicial district as a result of the employment relationship entered into in this Judicial District.

3. This Complaint arises from the denial of benefits and breaches of fiduciary duty by Defendants Teva Pharmaceuticals USA, Inc. Omnibus Welfare Plan, Quantum Health, Inc. which does business in California as Coordinated Healthcare; Meritain Health, Inc., MCMC, LLC and Aetna Life Insurance Co. (collectively, "Defendants"). Defendants failed to properly administer the Medical Benefit Section of the Teva Pharmaceuticals USA, Inc. Omnibus Welfare Plan that Plaintiff John Herzfeld ("Jack") participates in through his father's, Jeffrey Herzfeld, participation in the Teva Pharmaceuticals USA, Inc. Omnibus Welfare Plan. Defendants have improperly denied Jack coverage for an myoelectric elbow-wrist orthoses ("EWO").

4. Jack suffers from Duchenne Muscular Dystrophy, which has caused degeneration and weakness in his muscles such that he requires a wheelchair for mobility and effectively has no use of his arms without assistance. EWOs would return function to his arms and aid with assisted daily living activities for Jack, such as lifting, feeding himself and all other basic daily living tasks that require arm function.

5. The MyoPro orthosis manufactured by Myomo, Inc. is the type of device that could restore function to Jack's arms to assist him with his living needs at home. The MyoPro has been peer reviewed in numerous articles, it has been approved by numerous health insurance companies, and is registered with the Food and Drug Administration ("FDA").

6. Defendants have improperly denied benefits to Jack by refusing to cover the cost of the MyoPro orthosis on the grounds that the device is excluded from coverage because Defendants claim the device is "experimental or investigational" and not a covered expense. Given the widespread acceptance by the medical community and many health insurance companies, Defendants' motivation to deny coverage stems from their desire to reduce costs to the Plan evidenced by its employment of Quantum Health, Inc., a so-called "Care Coordinator," which describes it function as intercepting "unnecessary" costs and redirecting the insured's behavior thereby reducing overall costs to Quantum Health, Inc.'s customer, in this case, the Plan.

7. Defendants seek to deny coverage for the Myomo MyoPro by claiming that the device is "experimental and/or investigational" to treat Duchenne muscular dystrophy. The device is not being prescribed for the purpose of "treating" Duchene muscular dystrophy, but rather to restore function to Jack's arms to allow him to have some independence in his daily living activities. Standard or conventional treatments will not restore any function to Jack's arms because the effects of Duchene muscular dystrophy cannot be reversed. The MyoPro is the only device or treatment that can restore any such function.

II. THE PARTIES

8. Plaintiff John Herzfeld resides in Coto de Caza, Orange County, California. Jack is the son and dependent of Jeffrey Herzfeld, who, at all times relevant, was an employee of Teva Pharmaceuticals USA, Inc. ("Teva"), until March 2018.

9. Defendant Teva Pharmaceuticals USA, Inc. Omnibus Welfare Benefit Plan (the "Plan") is a qualified welfare benefit plan subject to ERISA with its principal place of administration located in North Wales, Pennsylvania. Teva is the Plan Sponsor and Plan Administrator of the Plan.

10. Defendant Quantum Health, Inc. which will do business in California

as Coordinated Healthcare ("Quantum") is a Delaware corporation and, on information and belief, administers the Medical Benefit Section of the Plan by acting as a "Care Coordinator" and handling appeals of medical benefit denials with respect to the Plan. As an administrator of the Plan, and exercising discretionary authority over the Plan, Quantum is a fiduciary of the Plan. Quantum's principal place of business is located at 7450 Huntington Park Drive, Columbus, OH 43235.

11. Defendant Meritain Health, Inc. ("Meritain") is a New York corporation with its principal place of business located in Amherst, New York. Meritain is identified in the Plan documents as the Claims Fiduciary and Third Party Administrator of the Plan.

12. Defendant Aetna Life Insurance Company ("Aetna") is a Connecticut corporation with its principal place of business located in Hartford, Connecticut. Health care services under the Plan are provided through Aetna's Aetna Choice® POS II, which serves as the network through which all health care services are provided except for plan participants in Utah, which utilizes a separate network.

13. Defendant MCMC, LLC ("MCMC") is a Delaware limited liability company with its principal place of business located in Quincy, Massachusetts. MCMC is an Independent Review Organization that conducts external reviews of benefit denials by health insurance companies and employment benefit plans.

III. GENERAL ALLEGATIONS

A. The Debilitating Effects of Duchenne Muscular Dystrophy

14. John is 18 years old and was diagnosed with Duchenne Muscular Dystrophy ("DMD") since age 6.

15. DMD is a genetic disorder characterized by progressive muscle degeneration and weakness. It is one of nine types of muscular dystrophy and is the most common form of the disorder. DMD is caused by flaws in the gene that controls how the body keeps muscles healthy leading to an absence of dystrophin, a protein that helps keep muscle cells intact. The disease almost always affects boys,

and symptoms usually begin early in childhood.

16. In the early stages, DMD affects the shoulder and upper arm muscles and the muscles of the hips and thighs. These weaknesses lead to difficulty in rising from the floor, climbing stairs, maintaining balance and raising the arms. Children with DMD have a hard time standing up, walking, and climbing stairs. Many eventually need wheelchairs to get around. By the early teens, the heart and respiratory muscles also are affected

17. Other symptoms of DMD include:

- A curved spine, also called scoliosis
- Shortened, tight muscles in the legs, called contractures
- Headaches
- Problems with learning and memory
- Shortness of breath
- Sleepiness
- Trouble concentrating

18. Long ago, children with DMD usually did not live beyond their teens. Today, because of available treatment and therapy, individuals with DMD commonly live well into their 30s, and can live into their 40s and 50s. As a result of the advances in treatment, persons with DMD can attend college, have careers, marry and raise children. The need for medical devices and therapies to assist with daily living for those with DMD increases by the day.

19. By the time a boy with DMD is twelve years old, he will most likely need a wheelchair to get around. Braces (orthoses) are commonly prescribed to support the ankle and foot and can extend over the knee. These types of orthoses are commonly worn at night to prevent the foot from pointing downward and to stretch the Achilles tendon while sleeping.

20. To minimize the impact of DMD, it is important to keep the body as flexible, upright and mobile as possible. There are several ways to do this. Standing

for a few hours each day, even with minimal weight bearing, promotes better circulation, healthier bones and a straight spine. A standing walker or standing frame can assist persons with DMD to stand. Some wheelchairs will raise the user into a standing position. Other mobility and positioning aids can help parents and caregivers.

21. As muscle deteriorates, a person with DMD often develops fixations of the joints, known as contractures. If not treated, these will become severe, causing discomfort and restricting mobility and flexibility. Contractures can affect the knees, hips, feet, elbows, wrists and fingers. Range-of-motion exercises, performed on a regular schedule, help delay contractures by keeping tendons from shortening prematurely. When contractures have advanced, surgery may be performed to relieve them. A tendon release procedure, also called heel cord surgery, is often done to treat ankle and other contractures while the child is still walking.

B. Jack's Current Condition and Daily Challenges

22. On April 20, 2017, Jack was examined by local Certified Prosthetist Orthotist, Tyra Rikimaru, to whom he was referred for a myoelectric orthotic evaluation. John was interested in a myoelectric orthotic "to optimize his physical activity to prevent further decompensation." Long term traditional therapies, such as stretching, standing frame regimes and swimming have not been successful in restoring any function for John. Based on his evaluation, Mr. Rikimaru found that Jack was an appropriate candidate for the MyoPro. He therefore referred Jack to Dr. Brandon Green, the Chief Medical Officer at Myomo, who is a licensed physician with training in rehabilitation medicine, subspecializing in prosthetic/orthotic rehabilitation, to do a chart review and approve or reject his recommendation that Jack be fitted with the MyoPro. Dr. Green reviewed Rikimaru's evaluation, spoke with Jack's pediatrician, Dr. Stephen Tang, and reviewed records from his office as well as those from Jack's physical therapist, Celeste Graham, and concluded that Jack is indeed a good candidate for a myoelectric orthotic to allow Jack to take

advantage of what remains of his muscle activity.

23. Jack requires an electric wheelchair to get around and "has upper extremity function effectively limited to his wrists/hands, while he can only move his elbows/shoulders when supine in gravity-eliminated positions." Until Fall 2018, Jack lived at home with his parents. Currently, Jack attends and lives at Arizona State University full time. Jack can steer his electric wheel chair, but requires assistance to set up his computer and writing to complete his homework. According to Dr. Green's review, Jack "requires maximum assistance for all other Activities of Daily Living (ADL) and Instrumental Activities of Daily Living (IADL) ADL/IADLs from his parents and care givers at school (e.g. bed mobility, hygiene, dressing, feeding, cooking, shopping, etc.)."

24. Jack "struggles with the total loss of his independence" and is "eager to learn to adopt additional assistive technology that will improve his independence and quality of life."

25. In 2009, Jack had Bilateral Achilles tendon lengthening to address his contractures. In 2012, Jack underwent a spinal fusion.

26. Because lost neuromuscular function from DMD damage cannot be reversed, powered assistance is the only available option for Jack to have any type of arm function. For years, Jack has tried traditional therapy without success. There is no other option available restore functionality to his arms other than a myoelectric EWO.

27. Dr. Green has opined that myoelectric orthoses are the best available technology to help Jack provide function to his arms:

> "Myoelectric EWOs are the only viable option for Jack, and there is a wealth of well-designed, peer-reviewed, published studies over the course of six decades which prove the standardized clinical efficacy and superiority of robotic, myoelectric technology over traditional, less sophisticated treatment alternatives for neurological impairments such as Jack's."

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C. The Myomo MyoPro Orthosis Restores Use and Function to Impaired Arms

28. Myoelectric orthoses were first created by Reinhold Reiter in Germany in the 1940s. Over the past 50 years, the technology has progressed from from single muscle control to "complex muscle group activity control." In the 1990s the Veterans Administration supported further research because it determined that myoelectric orthoses could benefit veterans who had upper extremity impairment. "In 2006, work in myoelectric upper extremity orthoses at MIT was commercialized resulting in the development of the Myo-Pro myoelectric elbow-wrist-hand orthosis (EWHO)"

29. Myomo, Inc. describes its myoelectric EWO, the MyoPro, as follows:

> "MyoPro is a powered orthosis (brace) designed to help restore function to arms and hands paralyzed or weakened by CVA stroke, brachial plexus injury, cerebral palsy or other neurological or neuromuscular disease or injury.
>
> MyoPro is a breakthrough in modern medical robotics. Originally developed at MIT with Harvard Medical School, it works by reading the faint nerve signals (myoelectric signals) from the surface of the skin (no implants) then activating small motors to move the arm and hand as the user intends (no electrical stimulation). The user is completely controlling their own hand and arm; the brace amplifies their weak muscle signal to help move the limb. It has been called 'power steering for your arm'."
>
> "While there are many prosthetic products for those who have lost their arms, hands or legs, and while there are orthotic products to support weak legs, MyoPro is the only product on the market to help restore function for those who still have their arms and hands but are unable to use them."
>
> The MyoPro may alleviate paralysis and allow a user to experience movement in the time it takes to put it on. It is the only device available that can immediately enable use of a paralyzed hand and arm. With the MyoPro, everyday tasks such as feeding and dressing may now be done again, everyday."

30. According to Myomo's CEO, "[i]t is the only device that, sensing a patient's own neurological signals through non-invasive sensors on the arm, can restore their ability to use their arms and hands so that they can return to work, live independently and reduce their cost of care."

31. The MyoPro is registered with the Food and Drug Administration ("FDA") as a class II medical device. It is "510(k) exempt" under the Food, Drug and Cosmetic Act from marketing clearance because of its low risk and proven safety. A 510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is at least as safe and effective as a legally marketed device (21 CFR § 807.92(a)(3)) that is not subject to premarket authorization. As a result, the MyoPro does not require FDA approval to be marketed. Myomo is compliant with FDA good engineering practices, is routinely recertified/audited by the FDA (most recently in 2018) and other independent bodies using international standards (ISO13485, MDSAP). Myomo has also obtained a CE Mark and a Canadian Medical Device license because of its high standards.

D. Acceptance of The MyoPro By Health Insurance Plans and Medical Institutions

32. There has been wide acceptance of myoelectric EWOs in the medical community. The MyoPro, such as the one that Jack seeks coverage for, has been approved by health insurance companies throughout the United States. For example, the MyoPro has been approved for coverage by the Blue Cross Blue Shield Association in the states of California, Colorado, Connecticut, Florida, Illinois, Indiana, Massachusetts, Michigan, Minnesota, New Jersey, New York, North Carolina, Ohio, South Carolina and Texas. Numerous other health insurance companies have approved the MyoPro[1]

33. In some cases, insureds have gone through the appeal process when a health insurance company and/or employee benefit plan has denied coverage for the MyoPro device and the insured prevailed. Insureds have prevailed in appeals against United Healthcare, Anthem and Medical Mutual, among others.

34. Medicaid plans in the states of California, Connecticut, Maine, New

[1] Among the health insurance companies that have covered the MyoPro are the following: Ascension, Aetna, Affinity, Ameriben, Amerigroup, Anthem, Carelink, Cigna, CoreSource, Emblem, Florida Hospital Care Advantage, Harvard Pilgrim, Humana, IEHP, Kaiser Permanente, Medical Mutual of Ohio, Neighborhood Health, Preferred One, Qualchoice, Tricare, Tufts, Unity, United Healthcare, Unity Health Insurance and the Veterans Affairs.

York and Pennsylvania have approved coverage for the MyoPro.

35. Numerous hospitals and medical institutions have accepted and used the MyoPro in their treatment of upper extremity impairment, including the Mayo Clinic, Johns Hopkins, Cleveland Clinic, Hospital for Special Surgery and the VA.

36. The determination by the above-referenced insurance companies, government agencies and medical institutions to cover and utilize the MyoPro and approve it as an accepted treatment for upper extremity impairment evidences that the MyoPro is neither experimental nor investigational. The safety, efficacy and effectiveness of myoelectric orthoses and prostheses have been provided through the more than fifty years of medical literature, studies and peer-reviews of the devices. One study found that "[m]yoelectric elbow-wrist-hand orthosis use significantly reduces UE [upper extremity] impairment and increases performance of certain functional tasks in chronic, moderately impaired stroke."[2]

37. Another article noted that "higher treatment intensity achieved using robot-assisted therapy is the most likely explanation for the enhanced results recorded in the upper extremities."[3]

38. A study of another Myomo orthosis, which was replaced by the MyoPro, noted that "[t]he study results support our hypothesis that a combined clinic-home robotic program integrating the affected arm into functional activities is feasible and a potentially effective therapeutic approach. . . . Participants demonstrated statistically significant improvements in both arm impairment and self-reported use of the arm from baseline to discharge; they continued to report significant improvement in actual use of the arm at 3-month follow-up."[4]

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[2] Peters HT, Page SJ, Persch A. Giving Them a Hand: Wearing a Myoelectric Elbow-Wrist-Hand Orthosis Reduces Upper Extremity Impairment in Chronic Stroke. Arch Phys Med Rehabil. 2017 Jan 24.

[3] Waldner A, Tomelleri C, Hesse S. Transfer of scientific concepts to clinical practice: recent robotassisted training studies. Funct Neurol. 2009 Oct-Dec;24(4):173-7.

[4] Kim GJ, Rivera L, Stein J. Combined Clinic-Home Approach for Upper Limb Robotic Therapy After Stroke: A Pilot Study. Arch Phys Med Rehabil. 2015 Dec;96(12):2243-8.

E. The Teva Pharmaceuticals USA, Inc. Omnibus Welfare Plan (Medical Benefits Section)

39. Effective January 1, 2017, Teva adopted the Medical Benefits Section ("MBS") of the Plan for the exclusive benefit of its employees and their eligible dependents. The purpose of the MBS is to "provide for the payment or reimbursement of all or a portion of certain health care expenses."

40. Under the heading of "Covered Medical Expenses," the Plan states:

> "Covered Expenses are the charges actually made for services provided to the Covered Person and only if the expenses are:
>
> (1) Routine care or preventive services provided such services are ordered and performed by a Physician and not otherwise excluded under the Plan; or
>
> (2) Due to Illness or Injury provided such services are ordered and performed by a Physician, Medically Necessary and not otherwise excluded under the Plan."

41. The Plan identifies various categories of Covered Expenses that the Plan will cover, including:

> "(22) Durable Medical Equipment: The rental of oxygen, wheelchairs, walkers, special Hospital beds, iron lungs and other Durable Medical Equipment subject to the following:
>
> (a) The equipment must be prescribed by a Physician and Medically Necessary;
>
> (b) The equipment will be provided on a rental basis; however, such equipment may be purchased at the Medical Benefit's option. Any amount paid to rent the equipment will be applied towards the purchase price. In no case will the rental cost of Durable Medical Equipment exceed the purchase price of the item (oxygen equipment is not limited to the purchase price);
>
> (c) Benefits will be limited to standard models as determined by the Medical Benefit."

42. In the Definitions section of the Plan, Durable Medical Equipment is defined as follows:

> "Durable Medical Equipment means equipment that:
>
> (1) Can withstand repeated use;
>
> (2) Is primarily and customarily used to serve a medical purpose;

(3) Generally is not useful to a person in the absence of an Illness or Injury; and

(4) Is appropriate for use in the home."

43. The MyoPro meets the definition of Durable Medical Equipment because it is: (1) designed to withstand repeated use; (2) used to serve a medical purpose (to treat upper extremity impairment); (3) not generally useful for someone who has full use of their arms; (4) appropriate for use in the home because it assists the user with basic living activities performed in the home.

44. Under the heading, "General Exclusions and Limitations" the Plan provides that, "[n]o payment will be eligible under any portion of the Medical Benefit for expenses Incurred by a Covered Person" for various listed expenses including:

> "(15) **Experimental and/or Investigational**: Expenses for treatment, procedures, devices, drugs or medicines that are determined to be Experimental and/or Investigational are not Covered Expenses, except for Off-Label Drug Use or when such expenses are considered Qualified Clinical Trial Expenses."

45. The Plan uses a "Care Coordination" process that is administered by Quantum:

> "This process includes a staff of Care Coordinators who receive a notification regarding most healthcare services sought by Covered Persons, and coordinate activities and information flow between the providers."

46. One of the explicit stated purposes of the "Care Coordination" process is to "help reduce unnecessary medical costs . . ." "The process" of care generally includes:

- Review and coordination process, including:
  - Pre-notification of certain procedures
  - Utilization Review
  - Concurrent Review of hospitalization and courses of care
  - Case Management

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47. The Plan requires "certain care, services and procedures be pre-certified before they are provided," including Durable Medical Equipment if the rental or purchase exceeds $500. Because the MyoPro costs significantly more than $500 (cost can exceed $20,000 for a single device), a participant or beneficiary of the Plan must obtain pre-certification before the MyoPro will be considered a covered expense.

48. A Pre-notification request is subjected to a utilization review to determine whether to approve the request:

> "The Care Coordinators will review each pre-notification request to evaluate whether the care, requested procedures, and requested care setting all meet utilization criteria established by the Medical Benefit. The Medical Benefit has adopted the utilization criteria in use by the Care Coordinators. If a pre-notification request does not meet these criteria, a medical director of Quantum Health will review the request, including all available information and if needed, will consult with the requesting provider. If required, the medical director will also consult with other professionals and medical experts with knowledge in the appropriate field. He or she will then provide, through the Care Coordinators, a recommendation to the Plan Administrator whether the request should be approved, denied, or allowed as an exception. In this manner, the Plan ensures that pre-notification requests are reviewed according to nationally accepted standards of medical care, based on community healthcare resources and practices."

49. "Final determinations regarding coverage and eligibility for benefits are made by the Medical Benefit."

50. The Plan outlines the claims procedures for participants to obtain coverage for various types of claims. For claims that require pre-approval, such as Durable Medical Equipment, the Plan provides the following:

> **"Pre-Service Claims.** For a pre-service claim, the Claims Fiduciary will notify you of the Medical Benefit's benefit determination (whether adverse or not) within a reasonable period of time appropriate to the medical circumstances, but not later than 15 days after the Claims Fiduciary receives the claim. If, due to matters beyond the control of the Medical Benefit, the Claims Fiduciary needs additional time to process a claim, the Claims Fiduciary may extend the time to notify you of the Medical Benefit's benefit determination for up to 15 days provided that the Claims Fiduciary notifies you within 15 days after the Claims Fiduciary receives the claim, of those special circumstances and of when the Claims Fiduciary expects to make its decision. . . .
>
> A claim for benefits is a pre-service claim if the claim requires approval, in part or in whole, in advance of obtaining the health care in

question."

51. If a claim is denied by the Claims Fiduciary, it must provide the following to the participant or beneficiary in writing or by electronic communication:

"(1) An explanation of the specific reasons for the denial;

(2) A reference to the Plan provision upon which the denial is based;

(3) A description of any additional information or material that you must provide in order to perfect the claim;

(4) An explanation of why the additional material or information is necessary;

(5) Notice that you have the right to request a review of the claim denial and information on the steps to be taken if you wish to request a review of the claim denial along with the time limits applicable to a request for review;

(6) A copy of any rule, guideline, protocol or other similar criterion relied upon, if any, in making the adverse determination (or a statement that the same will be provided upon your request and without charge); and

(7) If the adverse determination is based on the Plan's Medical Necessity, Experimental and/or Investigational treatment, or similar exclusion or limit, either: (a) an explanation of the scientific or clinical judgment applying the exclusion or limit to your medical circumstances or (b) a statement that the same will be provided upon your request and without charge.

Any notice of adverse determination also will include the following information:

(1) Information sufficient to identify the claim involved, including the date of service, the health care provider and the claim amount (if applicable);

(2) As part of the explanation of the determination, a discussion of the decision, as well as disclosure of any denial code used (and an explanation of its meaning) and a description of the Medical Benefit's standard, if any, that was used in denying the claim;

(3) A description of available internal appeals processes, including information regarding how to initiate an appeal;

(4) Contact information for the DOL's Employee Benefits Security Administration and any applicable state consumer assistance program; and

(5) A statement describing the availability, upon request, of any applicable diagnosis code (and an explanation of its meaning) and any applicable treatment code (and an explanation of its meaning)."

52. After a claim is initially denied, the participant or beneficiary can request a review of the adverse determination. If the "first level appeal" is denied, a second level appeal can be made. Any evaluation of an appeal must meet the following requirements:

> "(1) The Medical Benefit will provide a review that does not afford deference to the adverse determination that is being appealed and that is conducted by an appropriate named fiduciary of the Plan who did not make the adverse determination that is the subject of the appeal and who is not a subordinate of the individual who made that adverse determination.
>
> (2) The appropriate named fiduciary of the Plan will consult with a health care professional who has appropriate training and experience in the field of medicine involved in the medical judgment before making a decision on review of any adverse determination based in whole or in part on a medical judgment, including determinations with regard to whether a particular treatment, drug or other item is Experimental and/or Investigational or not Medically Necessary or appropriate. The professional engaged for purposes of a consultation in the preceding sentence will be an individual who is neither an individual who was consulted in connection with the adverse determination that is the subject of the appeal, nor a subordinate of any such individual.
>
> (3) The Medical Benefit will identify any medical or vocational experts whose advice is obtained on behalf of the Medical Benefit in connection with the Medical Benefit's review of an adverse determination, without regard to whether the advice is relied upon in making the adverse determination on review.
>
> (4) For a requested review of an adverse determination involving an urgent care claim, the review process will meet the expedited deadlines described below. Your request for such an expedited review may be submitted orally or in writing and all necessary information, including the Medical Benefit's determination on review, will be transmitted between the Medical Benefit and you by telephone, facsimile or other available similarly expeditious method.
>
> (5) The reviewer will afford you an opportunity to review and receive, without charge, all relevant documents, information and records relating to the claim and to submit issues and comments relating to the claim in writing to the Claims Fiduciary. The reviewer will take into account all comments, documents, records and other information submitted by the claimant relating to the claim regardless of whether the information was submitted or considered in the initial benefit determination.
>
> (6) You will be provided, free of charge, any new or additional evidence or rationale considered, relied upon or generated by the Medical Benefit in connection with the claim as well all documents, records, and other information relevant to the Claimant's Claim for benefits. Such documents, evidence, and rationale will be provided as soon as possible and sufficiently in advance of the Medical Benefit's

deadline for providing notice of its determination on review to give you a reasonable opportunity to respond prior to such determination.

(7) The Medical Benefit will ensure that all claims are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decisions.

(8) The Medical Benefit will provide you with continued coverage pending the outcome of an internal appeal."

53. All requests for review of a denied medical claim must be submitted to Quantum.

54. If the second level appeal is denied, a request for an external review can be made to the Claims Fiduciary who will determine "whether the claim is eligible for the external review process." If the request is eligible, an independent review organization ("IRO") will be assigned by the Claims Fiduciary to conduct an external review.

55. The Plan sets fort the following requirements for an external review:

"(4) The assigned IRO will notify you in writing (within a reasonable period of time) of the request's eligibility and acceptance for external review. The notice will include a statement regarding your right to submit any additional information, within 10 business days from the date of receipt of the notice, for the IRO to consider as part of the external review process. Any such additional information received by the IRO will be forwarded on and shared with the Claims Fiduciary. The Claims Fiduciary, based upon any new information received, may reconsider its final internal adverse determination. Reconsideration by the Claims Fiduciary will not delay the external review process. If the Claims Fiduciary does not reconsider its final internal adverse benefits determination, the IRO will continue to proceed with the external review process.

(5) Within 45 days after the IRO receives the external review request from the Medical Benefit, the IRO must provide written notice of its external review determination to you and the Medical Benefit. The IRO's notice is required to contain the following:

(a) A general description of the reason for the request for external review, including information sufficient to identify the claim, the diagnosis code and treatment code and the corresponding meaning for each and the reason for the previous denial;

(b) The date the IRO received the assignment to conduct the external review and the date of the IRO decision;

(c) References to the evidence or documentation, including the specific coverage provisions and evidence based standards, considered in reaching its decision;

> (d) A discussion of the principal reason or reasons for its decision, including the rationale for its decision and any evidence-based standards that were relied on in making its decision;
>
> (e) A statement that the determination is binding except to the extent that other remedies may be available under State or Federal law to either the group health plan or to you;
>
> (f) A statement that judicial review may be available to you; and
>
> (g) Contact information for the DOL's Employee Benefits Security Administration and any applicable state consumer assistance program."

56. The external review determination is binding on both the Plan and the claimant, "except to the extent that other remedies are available under applicable State or Federal law." The external review is the last available review of an adverse determination by the Plan.

F. Jack Exhausted All Known Internal and External Appeals Procedures

57. On or about March 4, 2017, Jack's pediatrician, Dr. Stephen Tang, recommended that Jack receive a myoelectric device such as the Myomo MyoPro. To support the medical necessity of Jack's request, on April 20, 2017, Jack was examined and evaluated by Tyra Rikimaru, a certified prosthetist/orthotist.

58. Dr. Green reviewed Jack's multidisciplinary medical record and prepared a written history and physical exam review dated May 22, 2017, to demonstrate the need and benefit by Jack for the Myomo orthosis.

59. Dr. Green made the following assessments and observations regarding Jack's condition:

> "His musculoskeletal symptoms are functionally limited to severe bilateral leg and arm weakness (proximal > distal), with total loss of the myriad functions of these extremities including all ADL/IADL function. . . While he is able to live at home and attend high school, Jack is rendered fully dependent on family and school staff who assist him on a daily basis for all ADL/IADLs. . . he seems to be benefitting from a relative stabilization of his condition, and his life expectancy ought to exceed the average for this condition by decades, particularly as the field of gene therapy continues to advance."
>
> "Functionally and clinically, Jack is equivalent to a bilateral shoulder disarticulation amputee, being fully reliant on others for completion of his ADL/IADLs. Objectively, he is over 7 times more disabled than the average American for basic daily function."

60. Dr. Green found that "Jack is an excellent candidate for myoelectric elbow-wrist orthoses fitting" because:

> "the long term, at-home use of which will greatly restore his lost arm functions, mitigate the additional risk to his overall health posed by inactivity, increase his independence at home and efficacy at school, while decreasing the burden on his family and insurers for his long term care."

61. In a letter dated June 20, 2017, Quantum denied Jack's request for coverage. Leslie Roth, RN, Nurse Care Coordinator for Quantum stated:

> "we are unable, according to the summary plan description language, to certify this request as this device is considered to be experimental or investigational because the effectiveness has not been established for the indication. Our TEVA Pharmaceuticals USA, Inc. health benefit plan excludes coverage for 'expenses for treatment, procedures, devices, drugs or medicines that are determined to be Experimental and/or Investigational.'"

62. Ms. Roth informed Jeffrey Herzfeld that Quantum would provide a clinical rationale for the non-certification upon request. In addition, Ms. Roth indicated that Dr. Tang could request a peer to peer discussion regarding the determination by calling Ms. Roth.

63. Jack's pediatrician, Dr. Stephen Tang, requested a peer-to-peer review, which occurred on or about August 9, 2017. Quantum, on behalf of the Plan, upheld the decision to deny coverage for the MyoPro.

64. In a letter dated September 21, 2017, Dr. Brandon Green, on behalf of Jack submitted Jack's first appeal of the denial of coverage to Quantum. In the letter, Dr. Green stated that his prior History and Physical Exam dated May 22, 2017 included Jack's medical records and "18 citations from published, peer-reviewed scholarly literature in support of the clinical efficacy of the care being requested." He noted that the initial denial was "without any specific consideration whatsoever for the objective evidence [Dr. Green] and Dr. Tang previously presented, which disproved the experimental label erroneously applied to the myoelectric orthoses that Mr. Herzfeld needs to restore arm function."

65. Dr. Green explained that Jack had the necessary muscle signals to use

the MyoPro and provided objective evidence that the MyoPro has been widely accepted by health insurance plans, including Quantum, and physicians:

> "Jack has been found to have robust, intact EMG signals in his bilateral biceps and triceps such that he can control myoelectric elbow-wrist orthoses to restore volition control of his elbows and allow reaching/positioning of his arms in space. The requested devices (MyoPro Motion W) are FDA registered and proven in the peer reviewed literature, have been covered by many public and private health insurance plans, including other Quantum Health plans, and are routinely prescribed by rehab physicians and surgeons in specialty rehab centers throughout the US."

66. Along with a letter explaining the basis for Jack's need for the MyoPro, Dr. Green included (1) a release of medical records and designation to allow Dr. Green to represent Jack, (2) the History and Physical Exam Review dated May 22, 2017 prepared by Dr. Green, (3) Quantum's letter dated June 20, 2017, initially denying coverage for the MyoPro and (4) a research article published in the Archives of Physical Medicine and Rehabilitation, entitled, "Giving Them a Hand: Wearing a Myoelectric Elbow-Wrist-Hand Orthosis Reduces Upper Extremity Impairment in Chronic Stroke" by Heather T. Peters, Stephen J. Page and Andrew Persch.

67. On November 1, 2017, the Plan, through Quantum, denied Jack's first appeal. In the letter, Sarah Bantner, a Quantum Appeals Coordinator, stated:

> "The appeal letter, along with all submitted clinical information, was forwarded to an independent Medical Reviewer of like specialty for consideration. The Medical Reviewer upheld the original decision, as the requested treatment was determined to be experimental / investigational per the Plans' language. The following is the rationale:
>
> '*National criteria considers robotic-assisted rehabilitation of the upper limb experimental and investigational for the treatment of neuromuscular diseases because of insufficient evidence of its effectiveness. Additionally, there is no literature to support the use of the requested prosthetic for the treatment of Duchenne muscular dystrophy.*'"

68. Inexplicably, Quantum referred to the MyoPro as a prosthetic, which is used for amputees, a use that the MyoPro is not intended.

69. By a letter dated November 9, 2017, Dr. Green filed on behalf of Jack a second appeal to Quantum. In his letter, Dr. Green took issue with the vague

reference to "national criteria" with respect to "robotic-assisted rehabilitation of the upper limb." Dr Green noted that "[a]s a licensed rehabilitation physician and board certified prosthetist subspecializing in prosthetic/orthotic rehab," he was not aware of any such "national criteria."

70. Dr. Green also countered Defendants' claim that the MyoPro was experimental and investigational, stating that:

> such a finding would fly in the face of decades of peer-reviewed literature, already cited and summarized in my previous submissions, which show the opposite. The use of powered orthoses for rehab and functional restoration of chronically weak arms is in fact well proven and satisfies even Quantum's own policy definitions so as to not be labeled experimental. Specifically:
>
> 1. The requested device is FDA registered (#:3006240003).
> 2. Its use is not governed anywhere by IRB approval (either in public or private sectors)
> 3. It is not undergoing Phase I, II, III trials, as its use, safety, and efficacy have long been established by decades of peer-reviewed literature already discussed in previous appeals.
> 4. Prevailing opinion among experts regarding the device is that it is fit and ready for routine clinical use – not needing further studies before broad implementation.
>
> Criteria number 4 is worth elaborating on in this case, because orthoses like those requested for Mr. Herzfeld are in fact accepted as appropriate medical practice for the treatment of chronic arm weakness due to a wide variety of etiologies (e.g. CVA, TBI, SCI, BPI, genetic conditions, etc.) and routinely prescribed in specialty rehab centers across the country (Mayo Clinic, Johns Hopkins, MGH, Cleveland Clinic, Hospital for Special Surgery, the VA, et al.). This again demonstrates compliance with Quantum policy by showing adoption by a substantial, qualified, responsible, relevant segment of the appropriate medical community and governmental oversight agencies. Indeed, this is because its efficacy has been shown to be often superior to standard treatments.

71. Lastly, Dr. Green took issue with the prior reviewer's lack of understanding of the MyoPro device:

> Finally, the previous medical reviewer asserted that 'there is no literature to support the use of the requested prosthetic [sic] for the treatment of Duchenne muscular dystrophy.' That comment is simply irrelevant to this kind of treatment, and it suggests that the reviewer does not understand either the care requested (they are orthoses for impaired albeit intact limbs, not prostheses for amputation) or regulatory and clinical standards around durable medical equipment. Clinical and regulatory decision making in the use of technologies such as this are governed by physical presentation, not physiological

> etiology. By way of comparison, ankle-foot orthoses are used for patients with ankle instability/weakness due to any number of causes (e.g. diabetic neuropathy, idiopathic neuropathy, traumatic peripheral nerve damage, stroke, etc.). No knowledgeable clinician or regulator would restrict their use based on specific diagnosis; they are proven to prevent foot drop and provide safe ambulation based upon outward physical parameters regardless of internal pathophysiology. That is why orthotics/prosthetics are not restricted by FDA indication labeling, as in the case pharmaceuticals (which is perhaps where Quantum's reviewer is drawing his standard from). Or, put another way, there is no 'off-label' usage of an orthosis; physical criteria is all that matters.

72. In a letter dated November 20, 2018, Quantum issued its denial of Jack's second appeal. Again, Sarah Bantner of Quantum issued the denial letter. Ms. Bantner used her prior letter dated November 1, 2017 and made a few minor changes, but the letter was essentially a carbon copy of the prior denial letter. The only material difference was that the rationale section was minimally modified to remove the erroneous reference that the MyoPro was a prosthetic device after it was pointed out by Dr. Green:

> "*National criteria considers robotic-assisted rehabilitation of the upper limb experimental and investigational for the treatment of neuromuscular diseases because of insufficient evidence of its effectiveness. Additionally, this device is considered to be experimental and investigational according to plan language because the prevailing opinion among experts regarding this device is that further studies or clinical trials are necessary to determine its safety, its efficacy, or its efficacy as compared with a standard means of treatment.*"

73. Ms. Bantner notified Jack that he had exhausted the internal appeal process for the Plan and could request an external review. Neither of Ms. Bantner's letters informed Jack that he could file a civil action if he disagreed with Quantum and the Plan's determination nor the time limit for filing such an action.

74. To avoid litigation and with the (false) hope of receiving an impartial review of Quantum's denials, Jack requested an external review by letter dated March 1, 2018.

75. Quantum assigned Jack's external appeal to its self-selected, contracted "Independent" Review Organization, Defendant MCMC. MCMC prides itself on claiming to have helped its "clients save over $200 million in abusive pre-pay and post-pay claims in the past four years."

76. MCMC issued its reviewer's decision on the external appeal by letter dated April 4, 2018, in which MCMC informed Jack that it was upholding Quantum and the Plan's coverage denial for the MyoPro on the ground that it was "experimental and investigational," stating as follows:

> **"Review Question:**
> **Is the requested service a Plan/Benefit exclusion as defined by the Summary Plan Description?**
>
> Yes. The requested service is a Plan/Benefit exclusion as defined by the Summary Plan Description.
>
> The Plan defines Experimental and/or Investigational as:
>
> 1. If the drug or device cannot be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and approval for marketing has not been given at the time the drug or device is furnished then it is deemed to be Experimental and/or Investigational; or
>
> 2. If the drug, device, medical treatment or procedure, or the patient informed consent document utilizing the drug, device, medical treatment or procedure, was reviewed and approved by the treating facility's Institutional Review Board or other body serving a similar function, or if federal law requires such review or approval, then it is deemed to be Experimental and/or Investigational; or
>
> 3. Reliable evidence shows that the drug, device, medical treatment or procedure is the subject of on-going Phase I or Phase II clinical trials, or is the subject of research, Experimental, study or Investigational arm of an ongoing Phase III clinical trials, or is otherwise under study to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with a standard means of treatment or diagnosis, then it is deemed to be Experimental and/or Investigational; or
>
> 4. Reliable evidence shows that the prevailing opinion among experts regarding the drug, device, medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with a standard means of treatment or diagnosis, then it is deemed to be Experimental and/or Investigational."
>
> The medical literature regarding this type of device is limited to preclinical work, developmental work and small anecdotal reports reporting potential for benefit (e.g., Ren Y, et al., 2013; Maciejasz P, et al., 2014; Proietti T, et al., 2016; Peters HT, et al., 2017), some of which is industry-sponsored work. It is not well known whether users will adopt the device for regular functional use in the long-term (i.e., for use beyond the short-term as a novelty device), or if the device itself causes injuries with long-term use (e.g., at the shoulder due to the device's weight). Current commercially available iterations of this type of device remain heavy, bulky, difficult to don/doff (typically using

> total assist from others), and impractical to use on a regular basis. Further study is required to determine its efficacy and safety as a health service. The device is not reasonably expected to favorably impact the member's long-term clinical or functional outcomes. It is experimental and investigational and therefore a Plan/Benefit exclusion as defined by the Summary Plan Description."

77. In upholding Quantum and the Plan's decision, MCMC failed to acknowledge, address or consider the detailed information provided by Jack or his providers, including the many referenced, contemporaneous studies and supporting documentation, and merely rubber-stamped Quantum and the Plan's position without analysis.

78. The MyoPro satisfies the four criteria to avoid the "Experimental and/or Investigational" exclusion:

a. It is not required to be FDA approved because it is exempt under the FDA's regulations and is FDA registered (#3006240003), as required.

b. It does not require review or approval by in independent review board nor does federal law require such review or approval;

c. It is not subject to or undergoing a Phase I, II, III trials because its use, safety, and efficacy has long been established; and

d. Reliable experts regard the device as ready for use and that further studies are not required to determine its safety, efficacy or effectiveness.

79. The denial sarcastically stated that Jack's parents **"came across"** the Myomo MyoPro. Furthermore, the denial mischaracterizes Jack's request for coverage under the Plan as "seeking funding for purchase of the device for the member's use." The cynical tone of the denial demonstrates the systemic bias toward denying coverage.

80. Further evidence that the a "full and fair" review was not undertaken by MCMC in the external review process is that the same reviewer, Reviewer ID 552, appears to cut and paste and reuse language for other external reviews of the MyoPro authored by Reviewer ID 552.

81. Erroneous information in the MCMC external review demonstrates that

the reviewer either misunderstood Jack's condition or did not bother to review Jack's records in any detail or at all. For example, the written external review erroneously states on page 2 under the heading "Case Information" that Jack's diagnosis is "[u]nspecified infantile cerebral palsy. Cerebral palsy is a brain injury or brain malformation that occurs while the brain is developing — before, during, or after birth. DMD is a genetic condition that does not involve a brain injury.

82. Among the documents and records the reviewer claimed to have reviewed was an unspecified "Aetna Clinical Policy Bulletin." A review of Aetna's Clinical Policy Bulletins on its website reveals that Aetna has not created a Clinical Policy Bulletin for myoelectric upper limb orthoses. Thus, it is unclear what Clinical Policy Bulletin the reviewer could have relied upon to support his or her determination, which further calls into question the basis for the determination.

83. MCMC's letter did not identify the reviewer, other than by number, who made the decision on behalf of MCMC. The following (inadequate) background information regarding the reviewer's qualifications was provided:

> **Reviewer #552:**
> I am board certified in Physical Medicine & Rehabilitation. I began practicing in 2002 and am currently Attending Staff at a hospital in the northeast and a Clinical Assistant Professor at its affiliated medical school. My areas of expertise include rehabilitation of neurological, orthopedic, and musculoskeletal disorders. I am published in the peer reviewed medical literature.

84. Nothing in this summary indicates that the reviewer had any training or experience with DMD and its related treatments, or with patients like Jack who suffered from DMD. Nor did the reviewer indicate that he or she had any experience with upper limb myoelectric orthoses. In fact, the letter exhibits a complete misunderstanding and lack of knowledge of the device on the part of the reviewer. MCMC therefore did not use a reviewer who was qualified to make a judgment about the safety and effectiveness of the MyoPro to assist someone with DMD.

85. The unidentified reviewer claimed that the MyoPro device was bulky,

heavy and impractical to use. The MyoPro is fabricated from light weight thermoplastics, among other materials; a MyoPro orthosis weighs little more than 2 pounds, which weight is distributed between the elbow and hand. The MyoPro is anything but heavy and bulky. The weight is easily tolerated by an adult such as Jack. Furthermore, the MyoPro is not impractical. Rather, it is the only practical means for Jack and others who suffer from DMD to regain function of their arms.

86. The purpose of medical insurance is to provide insureds with coverage for both every day medical expenses and catastrophic events. Contrary to the view of MCMC, medical insurance is not viewed as a source of "funding" to the average insured, but rather as stated in the purposes of the Plan to assist with the payment of medical expenses that arise.

87. MCMC has a scheme and practice of denying claims for the MyoPro. On no less than three other occasions in approximately the last year, MCMC has conducted a purported impartial external review for the MyoPro at the request of United Healthcare, Independence Blue Cross and a separate request through Quantum, even though Quantum has previously agreed the Myomo device was a covered expense. On each occasion, MCMC has denied coverage for the MyoPro.

88. To ensure that a health insurance company will not have to provide coverage for the MyoPro, MCMC relies on the same reviewer, identified only as "Reviewer ID 552," to conduct the external review of the MyoPro. Despite the fact that MCMC claims to have the "largest panel of credentialed reviewers," it uses the same reviewer each time it conducts an external review of coverage for the MyoPro. It is no coincidence that the same individual reviewed the MyoPro each time and coverage for the MyoPro was denied each time. Use of the same reviewer who denies coverage for the MyoPro every time a review is conducted violates the requirement that the external review be impartial. In addition, it evidences a bias by MCMC to ensure that it satisfies its mission to save its customers money by denying coverage for medical claims. In many cases, the MCMC reviewer, Reviewer ID

552, simply cut and pasted language from other denials of the MyoPro the reviewer authored evidencing a predisposed position to deny coverage for the device without conducting a full and fair review.

89. MCMC has placed its economic interests above those of claimants such as Jack by denying claims for the MyoPro to ensure that it continues to receive business from the health insurance companies. By denying high cost claims such as Jack's, MCMC saves money for the health insurance companies and remains a preferred IRO.

90. Jack has repeatedly and in good faith exhausted all known available appeals avenues under the Plan to convince Defendants to provide coverage properly for Jack's claim for the MyoPro orthoses, including exhausting the internal and external review process set forth in the Plan.

91. Jack made numerous requests and appeals demanding that Defendants reverse their previous benefit denials, promptly pay the previously submitted claim for the MyoPro orthosis, and conform its medical policies and claims systems programming so that Defendants' recognize their obligation to pay for the MyoPro and similar orthosis as a covered benefit.

92. As of the date of this Complaint, Defendants have failed to comply in full with these demands.

93. This action is timely commenced within twelve months from the date Jack was notified by Defendants that it was finally rejecting Jack's claim for coverage of a myoelectric EWO and that he could no longer appeal Defendants' denial.

IV. CAUSES OF ACTION

COUNT ONE

(Claim for ERISA Benefits)

94. Jack incorporates by reference the allegations of paragraphs 1 through 83 as if set forth at length herein.

95. Jack files this action pursuant to ERISA §502(a)(1)(B), 28 U.S.C. §1132, to recover benefits due him as a beneficiary of an ERISA plan.

96. As a beneficiary of the Plan, Jack is entitled to recover benefits due him and enforce his rights under the terms of the Plan.

97. The Plan requires benefit coverage of medical expenses incurred by Jack at usual, customary, and reasonable rates.

98. Defendants are obligated to approve and pay for medically necessary services, covered services, or covered benefits as defined under the Plan. As a beneficiary of the Plan, Jack is entitled to coverage of benefits under the ERISA-governed Plan for a myoelectric EWO because the Plan covers expenses for Durable Medical Equipment such as the MyoPro.

99. Defendants have breached the terms of the Plan by refusing to pre-certify charges covered by the Plan, in violation of ERISA 502(a)(1)(B), 29 U.S.C. § 1132(a)(1)(B).

100. As a result of, among other acts, Defendants' numerous procedural and substantive violations of ERISA, any appeals are deemed exhausted or excused, and Jack is entitled to have this Court undertake a de novo review of the issues raised herein. In addition, California Insurance Code § 10110.6(a) bans discretionary clauses in certain insurance policies, including health insurance policies rendering them void. Thus, to the extent the Plan retains discretionary authority to determine whether benefits will be paid, such discretion is prohibited under California law.

101. Moreover, pursuant to 29 U.S.C. § 1132(a)(1)(B), Jack is entitled to coverage of the Myomo MyoPro and reimbursement for the costs of the device as provided by the terms of the Plan. Jack is also entitled to declaratory and injunctive relief to enforce the terms of the Plans and to clarify his right to future benefits under such plan, as well as attorneys' fees.

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COUNT TWO

(Violation of Fiduciary Duties of Loyalty and Due Care in Violation of ERISA)

102. Jack incorporates by reference the allegations of paragraphs 1 through 83 as if set forth at length herein.

103. 29 U.S.C. § 1132(a)(3) states that a civil action may be brought by a "participant, beneficiary, or fiduciary to (A) enjoin any act or practice which violates any provision of this subchapter or the terms of the plan, or (B) to obtain other appropriate equitable relief (i) to redress such violations or (ii) to enforce any provisions of this subchapter or the terms of the plan."

104. Quantum, Meritain, MCMC and Aetna are fiduciaries under ERISA because the Plan is issued pursuant to an employee benefit plan and Quantum, Meritain, MCMC and Aetna all exercise discretionary authority or discretionary control respecting the management of an employment benefit plan and the disposition of its assets; and have discretionary authority in the administration of the Plan.

105. As ERISA fiduciaries, Quantum, Meritain, MCMC and Aetna owed Jack a duty of care, defined as an obligation to act prudently, with the care, skill, prudence and diligence that a prudent fiduciary would use in the conduct of an enterprise of like character. Further, as fiduciaries, Quantum, Meritain, MCMC and Aetna were required to ensure that there were acting in accordance with the documents and instruments governing the Plans and in accordance with ERISA § 404(a)(l)(B) and (D), 29 U.S.C. § 1104(a)(l)(B) and (D). In failing to act prudently, and in failing to act in accordance with the documents governing the Plan, Quantum, Meritain, MCMC and Aetna have violated their fiduciary duty of care.

106. Meritain, as the Claims Fiduciary of the Plan, had a duty to properly oversee the conduct of Quantum, Aetna and MCMC to ensure that they carried out their fiduciary duties pursuant to the terms of the Plan, which duty Meritain failed to do, by among other things, failing to ensure that Quantum followed all required

procedures during the appeal process and failing to ensure that MCMC conducted an impartial external review, which it did not.

107. As a fiduciary, Quantum, Meritain, MCMC and Aetna also owed Jack a duty of loyalty, defined as an obligation to make decisions in the interest of its beneficiaries, and to avoid self-dealing or financial arrangements that benefit the fiduciary at the expense of members, in accordance with ERISA § 404(a)(l)(A), 29 U.S.C. § 1104(a)(l)(A) and ERISA § 406, 29 U.S.C. § 1106. Thus, Quantum, Meritain, MCMC and Aetna could not make benefit determinations for the purpose of saving the Plan and Aetna money at the expense of the Plan's participants and beneficiaries.

108. Quantum, Meritain, MCMC and Aetna have violated their fiduciary duty of loyalty to Jack by, among other things, refusing to cover the Myomo MyoPro, to their own advantage, at the expense of the Plan's participants and beneficiaries.

109. Jack is entitled to relief to remedy Quantum, Meritain, MCMC and Aetna's violation of their fiduciary duties under ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), including declaratory, injunctive relief and attorneys' fees.

COUNT THREE

(Denial of Full and Fair Review in Violation of ERISA § 503)

110. Jack incorporates by reference the allegations of paragraphs 1 through 83 as if set forth at length herein.

111. As a beneficiary of the Plan, Jack is entitled to receive protection under ERISA, including (a) a "full and fair review" of all claims denied by Defendants; and (b) compliance by Defendants with applicable claims procedure regulations.

112. Although Defendants are obligated to provide a "full and fair review" of denied claims pursuant to ERISA § 503, 29 U.S.C. § 1133 and applicable regulations, including 29 C.F.R. § 2560.503-1 and 29 C.F.R. § 2590.715-2719, Defendants have failed to do so by, among other actions: refusing to provide the

specific reason or reasons for the denial Jack's claim; refusing to provide the specific rule, guideline or protocol relied upon in making the decision to deny Jack's claim; refusing to describe any additional material or information necessary to perfect a claim, such as the appropriate diagnosis/treatment code; failing to notify Jack of his right to judicial review of Defendants' denial of his claim and the time limit for bringing such a claim. By failing to comply with the ERISA claims procedures regulations, Defendants failed to provide a reasonable claims procedure.

113. Because Defendants have failed to comply with the substantive and procedural requirements of ERISA, any administrative remedies are deemed exhausted pursuant to 29 C.F.R. § 2560.503-1(l) and 29 C.F.R. § 2590.715-2719(b)(2)(ii)(F)(1). Finally, exhaustion would be futile because Defendants have adopted a clear policy of excluding coverage for the MyoPro.

114. Jack has been harmed by Defendants' failure to provide a full and fair review of appeals submitted under ERISA § 503, 29 U.S.C. § 1133, by Defendants' failures to disclose information relevant to appeals and to comply with applicable claims procedure regulations.

115. Jack is entitled to relief under ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), including declaratory and injunctive relief, to remedy Defendants' failures to provide a full and fair review, to disclose information relevant to appeals, and to comply with applicable claims procedure regulations.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff John Herzfeld respectfully requests that this Court grant the following relief:

A. Declaring that Defendants have breached the terms of the Plan and awarding payment for unpaid benefits, as well as awarding injunctive and declaratory relief to prevent Defendants' continuing actions detailed herein that are unauthorized by the Plan;

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B. Declaring that Defendants failed to provide a "full and fair review" under § 503 of ERISA, 29 U.S.C. § 1133, and applicable claims procedure regulations, as well as awarding injunctive, declaratory and other equitable relief to ensure compliance with ERISA and its claims procedure regulations;

C. Declaring that Defendants violated their fiduciary duties under § 404 of ERISA, 29 U.S.C. § 1106, and awarding injunctive, declaratory and other equitable relief to ensure compliance with ERISA;

D. Temporarily and permanently enjoining Defendants from continuing to pursue their actions detailed herein, and ordering Defendants to pay benefits in accordance with the terms of the Plan and applicable law;

E. Awarding restitution for reimbursements improperly withheld by Defendants;

F. Declaring that Defendants have violated the terms of the Plan and/or policies of insurance covering Plaintiff John Herzfeld;

G. Requiring Defendants to make full payment on all previously denied claims relating to Plaintiff John Herzfeld's request for coverage of a myoelectric EWO;

H. Requiring Defendants to pay Plaintiff John Herzfeld the benefit amounts as required under the Plan;

I. Awarding reasonable attorneys' fees, as provided by common law, federal or state statute, or equity, including Section 502(g) of ERISA, 29 U.S.C. § 1132(g);

J. Awarding costs of suit;

K. Awarding pre-judgment and post-judgment interest as provided by common law, federal or state statute or rule, or equity; and

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L. Awarding all other relief that the Court may deem just and proper.

Respectfully submitted,

DATED: November 20, 2018

DAVIS LAW GROUP, PLC

By: /s/ D. Jason Davis
D. Jason Davis
Attorneys for Plaintiff,